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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,413	04/15/2005	Rolf Neumann	PHDE020229US	8122

38107 7590 06/13/2008

PHILIPS INTELLECTUAL PROPERTY & STANDARDS
595 MINER ROAD
CLEVELAND, OH 44143

EXAMINER	
SAIDI, AZADEH	
ART UNIT	PAPER NUMBER
3735	
MAIL DATE	DELIVERY MODE
06/13/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/531,413	NEUMANN ET AL.	
	Examiner	Art Unit	
	Anita Saidi	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04/24/2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-10,12-15 and 22-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-10,12-15 and 22-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This office action is responsive to Applicant's arguments filed on April 24, 2008. Examiner acknowledges the amendments to claims 1 and 24-26 and cancellation of claim 3. Currently claims 1-2, 4-10, 12-15 and 22-26 are pending.

Response to Arguments

2. Applicant's arguments filed April 24, 2008 have been fully considered but they are not persuasive.

Regarding rejection of claim 1

Claim 1 has been rejected as being unpatentable under 35 USC 103(a) over US 4,109,643 to Bond et al and US 5,438,983 to Falcone.

Applicant argues that neither references nor the combination teaches defining a first perfusion index as a reference value selected from perfusion index value determined during the photometric measuring process and displaying the reference value on the display (Page 7). Applicant also argues that a medical practitioner using the device can not determine a measured reference perfusion index value in order to compare with the current perfusion index.

However, the examiner respectfully disagrees, in response to applicant's arguments against the references individually; one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Bond reference teaches a perfusion meter and a method of calculating the perfusion index which is displayed as a bar graph on the display (510 and Col. 6, line 65-Col. 7, line 7 of Bond). Falcone teaches a device that monitors physiological parameters and detects any trend between the current acquired values and the previous values in order to set an alarm if the values are above or below a predetermined threshold (Col. 2, lines 15-20 and lines 47-60 and Col. 5, lines 3658 of Falcone). Falcone also teaches that the physiological parameters can be displayed as waveforms or numerical values (Col. 3, lines 50-53 of Falcone). As explained in the previous office action the perfusion monitor of Bond as modified by Falcone, is capable of displaying a waveform of the physiological parameters measured as well as the current value and a bar graph representing the change in the parameter measured, and the length of the bar graph indicates the magnitude of change in the measured parameter. The display of these parameters on the display will allow the physician to look at the monitor and know what the parameter value has been doing over a specified time, for example during a 15 min window (Col. 5, line 65-Col. 6, line 28 of Falcone). The reference value in this situation can be any point in the specified window for example the starting point of the waveform graph in the predetermined window of time or any point in time during that specific period (Fig. 6 of Falcone).
The trend value displayed on the screen represents the direction and the amount of changes that have occurred since the previous physiological measurements. The language of claim 1, does not specify how the relative deviation is calculated, or what the deviation has been defined as. The Falcone reference is

capable of representing a deviation in the physiological parameters measured during the time the device is in use (Col. 4, lines 30-32 of Falcone).

Applicant also argues that the proposed Bond/ Falcon combination would not inform the medical personnel of whether a given patient has improved or regressed respective to a reference perfusion index value. However, the examiner respectfully disagrees, the alleged differences have not been positively claimed and also, as discussed previously, when the system detects any dramatic change within the acquired physiological data, the clinician is notified via an alarm system. Since the physiological parameters can be displayed in a specific time frame and the trend is also displayed on the screen, the clinician is well capable of judging the changes in the condition of the patient.

Applicant also points out that Falcone does not teach display of a perfusion index value nor the additional computational step. However, the examiner respectfully disagrees. As explained previously, the perfusion index monitor of Bond is capable of computing and displaying the perfusion index. Claim 1 has been rejected under 35 USC 103(a) and therefore the claim limitations have been rejected using the modified teachings of Bond and Falcone at the same time, not each reference individually.

Regarding the rejection claim 22

Applicant argues that the neither Bond and Falcone references nor the combination teaches a display configured to display a first graphical element indicative of a reference perfusion index at a reference time and a second graphical element providing perfusion data at a subsequent time. However, the examiner respectfully disagrees, the modified device of Bond and Falcone is capable of displaying the current perfusion value as well as a waveform graph in a set time period (Fig. 6 of Falcone). The reference value of the perfusion index can be any point on the graph, and therefore the combined references meet claim 22.

Applicant also argues that the combined reference is not capable of indicating whether the perfusion index reading is good or bad, and would fail to inform the medical practitioner of whether or not the current perfusion index reading is an improvement over the previous readings. However the examiner respectfully disagrees, as discussed earlier, since the system can display any of the physiological parameters as a waveform, the perfusion index can be displayed as a waveform and the trend of change can be displayed as a bar graph or numerical value. Therefore, the medical practitioner is able to determine the changes in the condition of the patient by looking at the waveform and the trend information displayed on the monitor.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-2, 7, 13-15, 22 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,109,643 to Bond et al (Hereinafter "Bond") in view of US 5,438,983 to Falcone (Hereinafter "Falone").

In reference to claims 1, 7 and 22:

Bond teaches:

A perfusion meter and a method of calculating perfusion index which comprises the steps of determining a perfusion index data for presentation (510 of Bond), using an algorithm from measured values produced by a non-invasive photometric measuring process for determining the arterial oxygen saturation of the blood (Col. 3, line 65-Col. 5, line 40 and Col. 5, line 60-Col. 6, line 17 of Bond). The device comprises a pulse oximeter (Fig. 6c of Bond) for determining arterial O_2 saturation and for providing perfusion data (Abstract of Bond); and a display unit (510 of Bond) configured to display the perfusion value. A perfusion value is determined and displayed as a bar graph (Col. 6, line 65-

Col. 7, line 7 of Bond). The recent perfusion index is compared with the previous value and the result will be displayed on the screen (Col. 7, lines 1-20 of Bond).

However, Bond fails to teach that:

A first perfusion index is defined as a reference value and subsequent perfusion indices are determined as relative deviations with respect to the reference value; and the reference value and the variation of the perfusion value are displayed on the display unit.

Falcone teaches:

A method and apparatus for detecting an alarm in a patient monitoring system. The values representative of physiological parameter of a patient are measured (Abstract of Falcone) using a sensor, such as pulse oximeter (16 and Col. 2, lines 6-10 of Falcone). A trend vector which is the function of changes in the parameter values and time will be calculated (Col. 2, lines 15-20 of Falcone). The processor includes means for displaying the trend vector on the display unit (24 of Falcone) as an arrow having direction that indicates a polarity of change in the parameter values. The arrow has a length that indicates the magnitude of change in the parameter (Fig. 6 and Col. 2, lines 47-60 of Falcone). The display can contain information such as waveforms or

current parameter values (Col. 6, lines 1-10 of Falcone). The relative deviation of the perfusion is presented in numerical form and the reference value is displayed in numerical form (Col. 3, lines 50-60 of Falcone).

Therefore it would have been obvious to one having ordinary skill in the art at the time the applicant's invention was made to have displayed a trend of the change in the values of the physiological parameters collected, similar to the teachings of Falcone, with the perfusion meter of Bond, in order to monitor the trend of change in the physiological parameter, so that the physician or health provider could look at the monitor and know, not just what the current parameter values are, but what the parameter values have been doing over a specified time (Col. 6, lines 22-28 of Falcone). It would have also been obvious to have replaced the display system of Bond with the one taught by Falcone in order to be able display different physiological parameters of the patient on the same screen this would give the clinician more information regarding the health status of a patient.

In reference to claim 2:

The reference value can be selected automatically at the beginning of the photometric measuring process or it is selectable from perfusion index values during the photometric measuring process (any point on the trend

vector of Falcone displayed on the display unit can be considered a reference value).

In reference to claim 4:

The reference value is stored on a memory chip (memory system 22 of Falcone).

In reference to claims 13-15:

An upper alarm limit and a lower alarm limit are provided.(52,54 and 40 and 44 of Falcone), wherein the alarm limit is adjustable (Col. 4, lines 44-55 of Falcone). An alarm signal is triggered when the alarm limit is exceeded (Col. 5, lines 55-58 of Falcon).

In reference to claim 26:

The display unit is further configured to display arterial O_2 saturation determined by the pulse oximeter (Fig. 6 of Falcone).

5. Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bond in view of Falcone as applied to claim 1 above and further in view of US 6,658,276 to Kianl et al (Hereinafter "Kianl").

In reference to claims 5 and 6:

Bond as modified by Falcone teaches all of the claim limitations;

see the rejection of claim 1 above.

However, the combination fails to teach that:

> The reference value, as well as the subsequent perfusion indices, are scaled by a factor which is adjustable.

Kianl teaches:

> A pulse oximeter user interface which comprises a display and a plurality of views. Each of the views are adapted to present data responsive to a physiological signal. One of the views is a pleth view that presents a pulse waveform. Another one of the views is a trend view that presents a trend graph (Abstract of Kianl). Kianl also discloses a method for representing variation in oxygen saturation and perfusion index, heart rate and other physiological information (Fig. 4 of Kianl). Kianl teaches the steps of deriving a pulse waveform responsive to a physiological signal, calculating a data trend responsive to the physiological signal and providing the pulse waveform in a first display view (Col. 2, lines 32-41 of Kianl). The reference value, as well as the subsequent perfusion indices, are scaled by a factor. (Col. 6, lines 10-15 of Kianl). The waveform is scaled based on the signal strength and therefore this factor is not fixed and is adjusted based on the strength of the signal.

It would have been obvious to one having ordinary skill in the art at the time the applicant's invention was made to have used a scaling factor similar to the one taught by Kianl in the perfusion meter of Bond as modified by Falcone, in order to adjust the screen to the change of the new parameter values, so that the new values can be better presented in the full screen.

6. Claims 8-10 and 23-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bond in view of Falcone as applied to claim 1 above, and further in view of US 6,322,516 to Masuda (Hereinafter "Masuda").

In reference to claims 8-10 and 23-25:

Bond as modified by Falcone teaches all of the claim limitations; see the rejection of claims 1 and 22 above.

However, the combination fails to teach that:

First and second analog graphic elements, such as bar graphs are used for the presentation of the reference value and the relative deviations, respectively. The relative variations of the perfusion are represented by a bar element and the reference value is represented by positioning of a reference graphic element respective to the bar element.

Masuda teaches:

An apparatus for monitoring change in value of physiological

parameters, such as blood-pressure and pulse oximetery values. The device obtains information using different monitoring apparatuses. The obtained information changes in relation to a change of the condition of the living subject (Col. 3, lines 32-43 of Masuda). A display (32 of Masuda) device is used which displays a first graphical representation of the obtained information, and a second graphical representation of the reference value, so that the first graphical representation can be compared to the previous information (Abstract of Masuda). The collected data is displayed as a bar graph, presenting a reference value, the variation of the current value relative to the reference value, and an arrow used to represent the reference value (this is shown as two superimposed bar elements in Fig. 8 of Masuda).

Therefore it would have been obvious to one having ordinary skill in the art at the time the applicant's invention was made to have used an analogue graphical element such as two superimposed bar elements similar to that taught by the blood pressure monitoring system of Masuda, in the perfusion meter of Bond as modified by Falcone in order for the medical staff to recognize, from the graph, to what degree each subsequent piece of information has deviated from the initial piece of information at the time of the last

measurement (Col. 4, lines 20-26 and Col. 17, line 65-Col. 18, line 20 of Masuda).

7. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bond in view of Falcone as applied to claim 1 above, and further in view of US 5,912,656 to Tham et al (Hereinafter "Tham").

In reference to claim 12:

Bond as modified by Falcone teaches all of the claim limitations; see the rejection of claim 1 above.

However, the combination fails to teach that:

The display is formed as a multidimensional type in conjunction with other physiological variables.

Tham teaches:

A device for producing a display from monitored data functions to read, store, encode, and integrate monitored data of at least one data type from at least one monitoring device so that the related or unrelated datum is comprehensible at a glance by a user. The system produces a single superimposed and/or multidimensional image capable of portraying a present and historical data combination reflecting the monitored data's relative value at some point in time (Abstract and Fig. 4 of Tham).

Therefore it would have been obvious to one having ordinary skill in the art at the time the applicant's invention was made to have used a known technique, such as displaying multiple types of data or a multidimensional image display as a means for displaying the collected data, for better comparison between the current record with the previously collected data, similar to the one taught by the display device of Tham, in the perfusion meter of Bond as modified by Falcone in order to improve the data presentation and provide a full report of the patient's physiological activity.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will

the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anita Saidi whose telephone number is (571)270-3001. The examiner can normally be reached on Monday-Friday 9:30 am - 6:00 pm Est.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. S./
Examiner, Art Unit 3735
6/13/2008

/Charles A. Marmor, II/
Supervisory Patent Examiner
Art Unit 3735